ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2006–0784; FRL–8096–4]

Bacillus Thuringiensis Modified Cry3A Protein and the Genetic Material Necessary for Its Production in Corn; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a permanent exemption from the requirement of a tolerance for residues of the *Bacillus thuringiensis* modified Cry3A protein (mCry3A) and the genetic material necessary for its production in corn on field corn, sweet corn, and popcorn when applied/used as a plant-incorporated protectant. Syngenta Seeds, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus thuringiensis* modified Cry3A protein (mCry3A) and the genetic material necessary for its production in corn.

DATES: This regulation is effective November 1, 2006. Objections and requests for hearings must be received on or before January 2, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0784. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8715; e-mail address: *mendelsohn.mike@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this ''**Federal Register**'' document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2006–0784 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before January 2, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2006–0784, by one of the following methods.

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of October 27, 2004 (69 FR 62688) (FRL–7370–1), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 4F6838) by Syngenta Seeds, Inc., P.O. Box 12257, 3054 Cornwallis Road, Research Triangle Park, NC 27709–2257. The petition requested that 40 CFR part 174 be amended by establishing a permanent exemption from the requirement of a tolerance for residues of modified Cry3A protein (mCry3A) and the genetic material necessary for its production in corn. This notice included a summary of the petition prepared by the petitioner Syngenta Seeds, Inc. One comment was received in response to the notice of filing from the National Corn Growers Association.

They supported the petition and requested EPA to quickly issue the final rule.

On March 14-15, 2006, EPA held a FIFRA Scientific Advisory Panel (SAP) meeting, at *http://www.epa.gov/scipoly/sap/meetings/2006/index.htm#march* to address the scientific issues that arose during the risk assessment of mCry3A. EPA asked the SAP to comment on the equivalence of the mCry3A proteins from corn event MIR604 and from recombinant *E. coli* - specifically the presence of two forms in the bacterial-produced mCry3A protein and the differences in bioactivity in the WCRM bioassay. The majority of the Panel concluded that the two forms of the mCry3A are of relatively comparable biological activity for the purposes of the human health assessments based on the amino acid sequence identity, lack of glycosylation, and general stability.

EPA also asked the SAP to comment on EPA's conclusions regarding the lack of mammalian toxicity and allergenicity of the mCry3A protein-specifically the impact of the less potent mCry3A form on the results of the acute oral toxicity tests and the usefulness of *in vitro* digestibility studies and amino acid sequence homology analysis as part of the risk assessment. Overall, the Panel was more concerned with the quality of data, i.e. inadequately described methods and poor reproduction of data images. The Panel specifically noted that the amino acid sequence analysis to known toxins and allergens were missing the following data: Specification of which version of NCBI database was utilized; descriptions of parameters utilized; and dates accessed for the BLAST search. EPA recognizes that these are important parameters to include in a description of an amino acid analysis and is requiring submission of additional information by Syngenta Seeds, Inc. in order to confirm the method used. However, EPA maintains that the conclusions of the amino acid sequence analysis are still valid for the purpose of the risk assessment. EPA reached this decision based on the following: (1) Lack of mammalian toxicity of mCry3A protein as shown by the acute oral mouse study; (2) mCry3A protein is rapidly digested in SGF; (3) mCry3A protein originates from a non-allergenic source; (4) lack of sequence identity of mCry3A protein with eight contiguous amino acids or more than 35% identity over 80 amino acids with known toxins or allergens; and (5) mCry3A protein is not glycosylated when expressed in corn.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .'' Additionally, section 408(b)(2)(D) of the FFDCA requires that the Agency consider ''available information concerning the cumulative effects of a particular pesticide's residues '' and ''other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Data have been submitted demonstrating the lack of mammalian toxicity at high levels of exposure to the mCry3A protein alone. These data demonstrate the safety of the products at levels well above maximum possible exposure levels that are reasonably anticipated in the crops. This is similar to the Agency position regarding toxicity and the requirement of residue data for the microbial *Bacillus thuringiensis* products from which this plant-incorporated protectant was derived (See 40 CFR 158.740(b)(2)(i)). For microbial products, further toxicity testing and residue data are triggered by significant acute effects in studies such as the mouse oral toxicity study, to verify the observed effects and clarify the source of these effects (Tiers II and III).

An acute oral toxicity study was submitted for the mCry3A protein. The acute oral toxicity data submitted support the prediction that the mCry3A protein would be non-toxic to humans. Male and female mice (5 of each) were dosed with 2,377 milligrams/kilograms bodyweight (mg/kg bwt) of mCry3A protein. With the exception of one female in the test group that was euthanized on day 2 (due to adverse clinical signs consistent with a dosing injury), all other mice survived the study, gained weight, had no test material-related clinical signs, and had no test material-related findings at necropsy.

When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (*Sjoblad, Roy D., et al.* ''Toxicological Considerations for Protein Components of Biological Pesticide Products,'' Regulatory Toxicology and Pharmacology 15, 3–9 (1992)). Therefore, since no effects were shown to be caused by the plant-incorporated protectants, even at relatively high dose levels, the mCry3A protein is not considered toxic. Further, amino acid sequence comparisons showed no similarity between the mCry3A protein and known toxic proteins available in public protein data bases. According to the Codex Alimintarius guidelines, the assessment of potential toxicity also includes stability to heat (FAO/WHO Standards Programme, 2001). Further data demonstrate that mCry3A is inactivated against Western corn rootworm, when heated to 95 °C for 30 minutes.

Since mCry3A is a protein, allergenic sensitivities were considered. Current scientific knowledge suggests that common food allergens tend to be resistant to degradation by acid, and proteases; may be glycosylated; and present at high concentrations in the food. Data have been submitted that demonstrate that the mCry3A protein is rapidly degraded by gastric fluid *in vitro*. In a solution of simulated gastric fluid 1 milligrams/milliliter (mg/mL) mCry3A test protein mixed with simulated gastric fluid (pH 1.2, containing 2 mg/mL NaCl, 14 µL 6 N HCl, and 2.7 mg/mL pepsin) resulting in 10 pepsin activity units/microgram (µg) protein (complies with year 2000 U.S. Pharmacopoeia recommendations),

complete degradation of detectable mCry3A protein occurred within 2 minutes. A comparison of amino acid sequences of known allergens uncovered no evidence of any homology with mCry3A, even at the level of eight contiguous amino acids residues. Further, data demonstrate that mCry3A is not glycosylated, and is present in low levels in corn tissue. Therefore, the potential for the mCry3A protein to be a food allergen is minimal. As noted above, toxic proteins typically act as acute toxins with low dose levels. Therefore, since no effects were shown to be caused by the plant-incorporated protectant, even at relatively high dose levels, the mCry3A protein is not considered toxic.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

The Agency has considered available information on the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances. These considerations include dietary exposure under the tolerance exemption and all other tolerances or exemptions in effect for the plant-incorporated protectant chemical residue, and exposure from non-occupational sources. Exposure via the skin or inhalation is not likely since the plant-incorporated protectant is contained within plant cells, which essentially eliminates these exposure routes or reduces these exposure routes to negligible. Exposure via residential or lawn use to infants and children is also not expected because the use sites for the mCry3A protein are all agricultural for control of insects. Oral exposure, at very low levels, may occur from ingestion of processed corn products and, potentially, drinking water. However, oral toxicity testing done at a dose in excess of 2 grams/kilogram (gm/kg) showed no adverse effects. Furthermore, the expression of the modified Cry3A protein in corn kernals has been shown to be in the parts per million range, which makes the expected dietary exposure several orders of magnitude lower than the amounts of mCry3A protein shown to have no toxicity. Therefore, even if negligible aggregate exposure should occur, the Agency concludes that such exposure would present reasonable certainty of no harm due to the lack of mammalian toxicity and the rapid digestibility demonstrated for the mCry3A protein.

V. Cumulative Effects

Pursuant to FFDCA section 408(b)(2)(D)(v), EPA has considered available information on the cumulative effects of such residues and other substances that have a common mechanism of toxicity. These considerations included the cumulative effects on infants and children of such residues and other substances with a common mechanism of toxicity. Because there is no indication of mammalian toxicity, resulting from the plant-incorporated protectant, we conclude that there are no cumulative effects for the mCry3A protein.

VI. Determination of Safety for U.S. Population, Infants and Children

A. Toxicity and Allergenicity Conclusions

The data submitted and cited regarding potential health effects for the mCry3A protein include the characterization of the expressed mCry3A protein in corn, as well as the acute oral toxicity, and *in vitro* digestibility of the proteins. The results of these studies were determined applicable to evaluate human risk, and the validity, completeness, and reliability of the available data from the studies were considered.

Adequate information was submitted to show that the mCry3A protein test material derived from microbial cultures was biochemically and functionally similar to the protein produced by the plant-incorporated protectant ingredients in corn. Production of microbially produced protein was chosen in order to obtain sufficient material for testing.

The acute oral toxicity data submitted supports the prediction that the mCry3A protein would be non-toxic to humans. As mentioned above, when proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Sjoblad, Roy D., et al. ''Toxicological Considerations for Protein Components of Biological Pesticide Products,'' Regulatory Toxicology and Pharmacology 15, 3–9 (1992)). Since no effects were shown to be caused by mCry3A protein, even at relatively high dose levels (2,377 mg/kg bwt), the mCry3A protein is not considered toxic. This is similar to the Agency position regarding toxicity and the requirement of residue data for the microbial *Bacillus thuringiensis* products from which this plant-incorporated protectant was derived. (See 40 CFR 158.740(b)(2)(i). Moreover, mCry3A showed no sequence similarity to any known toxin and was inactivated by heat against Western corn rootworm. No further toxicity testing and residue data were required because for microbial products, further toxicity testing and residue data requirements are triggered by significant acute effects in studies such as the mouse oral toxicity study to verify the observed effects and clarify the source of these effects (Tiers II and III).

Modified Cry3A protein residue chemistry data were not required for a human health effects assessment of the subject plant-incorporated protectant ingredients because of the lack of mammalian toxicity. However, data submitted demonstrated low levels of mCry3A in corn tissues with less than 2 µg mCry3A protein/gram dry weight in kernals and less than 30 µg mCry3A protein/gram dry weight of whole corn plant.

Since modified Cry3A is a protein, its potential allergenicity is also considered as part of the toxicity assessment. Data considered as part of the allergenicity assessment include that the modified Cry3A protein came from *Bacillus thuringiensis* which is not a known allergenic source, showed no sequence similarity to known allergens, was readily degraded by pepsin, and was not glycosylated when expressed in the plant. Therefore, there is a reasonable certainty that modified Cry3A protein will not be an allergen.

Neither available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers including infants and children) nor safety factors that are generally recognized as appropriate for the use of animal experimentation data were evaluated. The lack of mammalian toxicity at high levels of exposure to the mCry3A protein, as well as the minimal potential to be a food allergen demonstrate the safety of the product at levels well above possible maximum exposure levels anticipated in the crop.

The genetic material necessary for the production of the plant-incorporated protectant active ingredients are the nucleic acids (DNA, RNA) which comprise genetic material encoding these proteins and their regulatory regions. The genetic material (DNA, RNA), necessary for the production of mCry3A protein has been exempted under the blanket exemption for all nucleic acids (40 CFR 174.475).

B. Infants and Children Risk Conclusions

FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity.

In addition, FFDCA section 408(b)(2)(C) also provides that EPA shall apply an additional tenfold margin of safety, also referred to as margins of exposure (MOEs), for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different MOE will be safe for infants and children.

In this instance, based on all the available information, the Agency concludes that there is a finding of no toxicity for the mCry3A protein and the genetic material necessary for their production. Thus, there are no threshold effects of concern to infants and children when the mCry3A protein is used as a plant-incorporated protectant. Accordingly, the Agency concludes that the additional MOE is not necessary to protect infants and children, and that not adding any additional MOE will be safe for infants and children.

C. Overall Safety Conclusion

There is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to the mCry3A protein and the genetic material necessary for its production. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

The Agency has arrived at this conclusion because, as discussed above, no toxicity to mammals has been observed, nor any indication of allergenicity potential for the plant-incorporated protectant.

VII. Other Considerations

A. Endocrine Disruptors

The pesticidal active ingredient is a protein, derived from sources that are not known to exert an influence on the endocrine system. Therefore, the Agency is not requiring information on the endocrine effects of the plant-incorporated protectant at this time.

B. Analytical Method(s)

A method for extraction and ELISA analysis of mCry3A protein in corn has been submitted and found acceptable by the Agency.

C. Codex Maximum Residue Level

No Codex maximum residue levels exist for the plant-incorporated protectant *Bacillus thuringiensis* mCry3A protein and the genetic material necessary for its production in corn.

VIII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption from the requirement of a tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the

agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 29, 2006.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 174—AMENDED

■ 1. The authority citation for part 174 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 174.456 is revised to read as follows:

§ 174.456 Bacillus thuringiensis modified Cry3A protein (mCry3A) and the genetic material necessary for its production in corn.

Bacillus thuringiensis modified Cry3A protein (mCry3A) and the genetic material necessary for its production in corn is exempt from the requirement of a tolerance when used as plant-incorporated protectant in the food and feed commodities of field corn, sweet corn and popcorn. Genetic material necessary for its production means the genetic material which comprise genetic material encoding the mCry3A protein and its regulatory regions. Regulatory regions are the genetic material, such as promoters, terminators, and enhancers, that control the expression of the genetic material encoding the mCry3A protein.

[FR Doc. E6–18223 Filed 10–31–06; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA), Department of Homeland Security, Mitigation Division.

ACTION: Final rule.

SUMMARY: Base (1% annual chance) Flood Elevations (BFEs) and modified BFEs are made final for the communities listed below. The BFEs and modified BFEs are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

EFFECTIVE DATES: The date of issuance of the Flood Insurance Rate Map (FIRM) showing BFEs and modified BFEs for each community. This date may be obtained by contacting the office where the maps are available for inspection as indicated on the table below.

ADDRESSES: The final BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: William R. Blanton, Jr., CFM, Acting Section Chief, Engineering Management Section, Mitigation Division, 500 C Street SW., Washington, DC 20472, (202) 646–3151.

SUPPLEMENTARY INFORMATION: FEMA makes the final determinations listed below for the modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Mitigation Division Director has resolved any appeals resulting from this notification.

This final rule is issued in accordance with Section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67.

The Agency has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and FIRM available at the address cited below for each community. The BFEs and modified BFEs are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. As flood elevation determinations are not within the scope of the Regulatory Flexibility Act, 5 U.S.C. 601–612, a regulatory flexibility analysis is not required.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of Section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, flood insurance, reporting and recordkeeping requirements.

■ Accordingly, 44 CFR Part 67 is amended as follows:

PART 67—[AMENDED]

■ 1. The authority citation for Part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.11 [Amended]

■ 2. The tables published under the authority of § 67.11 are amended as follows: